

November 18, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 99-27

Subject: Solicitation of Representative Samples for International Collaborative Study

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

The Center for Veterinary Biologics (CVB) announces an opportunity for licensees and permittees to provide samples of licensed product serials for use in an international collaborative study. The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) Biologicals Quality Monitoring Working Group has identified an assay to be included in the proposed VICH Residual Formaldehyde Guideline. Samples of licensed bacterins are needed to evaluate the performance characteristics of the proposed assay. The purpose of this Notice is to identify Veterinary Biologics Establishments willing to provide biologics samples as indicated below.

The CVB, on behalf of the Working Group, will select one product from each of three categories, request receipt of at least 300 ml of the serial, aliquot the sample, label the aliquots with random numbers, and distribute as a coded experimental panel to those laboratories participating in the testing. A limited number of government and industry laboratories in each of the three VICH regions (United States, European Union, and Japan) will test the samples by their current assay and the proposed harmonized assay. The CVB will collect and distribute the data to the Working Group members for analysis. The study is intended to evaluate the reproducibility characteristics of the proposed assay and provide a data basis for future formaldehyde assay equivalency studies.

The CVB will select one product of each of the following three categories:

- An aluminum adjuvanted Clostridial bacterin containing residual formaldehyde levels of >0.8 but <2.0 gm/L
- An oil adjuvanted bacterin containing >0.05 but <0.8 gm/L formaldehyde
- A nonvirucidal bacterin, formaldehyde inactivated, but whose residual formaldehyde concentration has been reduced to <0.05 gm/L by the addition of sodium bisulfite

Contact Frank Ross, Toxicology and Chemistry Section, National Veterinary Services Laboratories (phone 515-663-7542, fax 515-663-7210), VICH Biologicals Quality Monitoring Working Group, Moisture and Formaldehyde Topic U.S. Government expert, if you wish your sample to be considered for the study. Submit the following information for each product by December 5, 1999: manufacturer number; product code number; expiration date; regions and/or countries to which the product is currently exported; and dose sizes available for donation. The CVB will not distribute the information, but will only use it as a basis for sample selection. The CVB will select products based on category, diversity of source, and other factors. The CVB will notify firms of the selected and nonselected products by December 15, 1999, and must receive samples by December 31, 1999, for inclusion in the study.

/s/ Randall L. Levings

Randall L. Levings
Director
Center for Veterinary Biologics